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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/202,305 | 03/22/1999 | NICHOLAS MANOLIOS | 06025.0003 | 2721 |

22428 7590 05/05/2004

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| EXAMINER |
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GUPTA, ANISH

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| ART UNIT | PAPER NUMBER |
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1654

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/202,305

Applicant(s)

NICHOLAS MANOLIOS

Examiner

Anish Gupta

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-15 is/are pending in the application.
- 4a) Of the above claim(s) 9-11, 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 6 and 13 is/are rejected.
- 7) ☒ Claim(s) 5, 7, 8 and 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6-24-03 has been entered.

Amendment

2. Along with the filing of the Request for RCE, Applicants requested that the amendment filed 5-20-03 also be entered. This amendment has been entered. Claim 1 was amended by the amendment. Claims 1, 3-14 are pending in this Application.

Election/Restrictions

3. Applicant's election with traverse of Group I and the species of SEQ ID. No. 7 in Paper No. 7 and 13 is acknowledged. Claims 1, 3-14 correspond to Group I.

Thus, as indicated in the previous office action, allowability was established for the species corresponding to SEQ ID NO: 6-15 and 17-26. Applicants have amended the claims and as such, the search was extended in the Markush group and a peptide was found that read on generic claim

Although claims 9-11 and 14 were examined with respect to SEQ ID. No 6-15 and 17-26, they were held as non-elected since they did not read on the elected species found in the prior art. Note that under species examination a claim can be held, even though the elected species may have read on the said claim, as non-elected.

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Claims 1, 3-4, 6 and 13 have been examined to the extent they read on the prior art. Claims drawn to the nonelected species, claims 9, 10-11, 14-15 are held withdrawn from further consideration.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 1, 3-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Kagan et al.

The claims are drawn to peptides that have a charged amino acid flanked by hydrophobic peptides that do not contain a charged amino acid.

The reference teaches the peptide Ala-Ala-Lys-Ala-Ala that meet the limitation of the claims (see abstract and page 11205, table II). The peptide read on the claimed invention because R1 is

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allowed to be NH₂, the N-terminus, the first X variable is allowed to be Ala-Ala, Z is Lys, the second X is Ala-Ala, and R₂ is COOH. Note that Alanine is conventionally known in the art to be a hydrophobic amino acid that is neutral. By virtue of having four Ala residues, the reference meet the limitation of claim 3, since 4 of the 5 amino acids are hydrophobic. Finally, although the reference does not teach that the peptides inhibit T-cell antigen receptor, such claimed language of is an intended use limitation and intended use or field of use. However, intended use limitation and intended use or field of use for the invention generally will not limit the scope of a claim. Moreover, where the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been established. In re Best, 195 USPQ 430, 433 (CCPA 1977). “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” In re Spada, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, *supra*. Here the reference disclose a peptide that meets all of the structural limitations, and accordingly claimed limitations are met.

Therefore, the reference anticipates the claimed invention.

5. Claims 1, 3, 6, 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Arrhenius et al. (US 5936065).

The claims are drawn to peptides that have a charged amino acid flanked by hydrophobic peptides that do not contain a charged amino acid.

The reference teaches CS-1 peptides and pharmaceutical compositions thereof that are effective in treating immunoinflammatory conditions (see abstract). The reference discloses

peptide NH₂-Ile-Leu-Asp-Val-Pro-COOH₂ as one of the peptides that is effective to treat immunoinflammatory conditions (see col. 65-66, 3rd compound from the top). The reference discloses numerous pharmaceutical formulations of the peptides including prodrug from (see col. 128-129). This teaching meets the limitation of claim 13. The peptide read on the claimed invention because R1 is allowed to be NH₂, the first X variable is allowed to be Ile-Leu, Z is Asp, the second X is Val-Pro, and R2 is COOH. Note that Ile, Leu, Val, Pro are all conventionally known in the art to be a hydrophobic amino acid that is neutral. By virtue of having these amino acids residues, the reference meet the limitation of claim 3. The presence of Asp meet the limitation of claim 6.

Finally, although the reference does not teach that the peptides inhibit T-cell antigen receptor, such claimed language of is an intended use limitation and intended use or field of use. However, intended use limitation and intended use or field of use for the invention generally will not limit the scope of a claim. Moreover, where the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been established. In re Best, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, *supra*. Here the reference disclose a peptide that meets all of the structural limitations, and accordingly claimed limitations are met.

Therefore, the reference anticipates the claimed invention.

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6. Claims 5, 7-8, and 12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims for the reasons set forth in the previous office action and the reasons set forth below.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can normally be reached on (703)306-3220. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Anish Gupta #1/12/04